Supreme Court, U.S.
FILED
JAN 3 - 2011
OFFICE OF THE CLERK

No. 09-1354

In the Supreme Court of the United States

ASS'N OF AM. PHYSICIANS & SURGEONS, INC., *ET AL.*,
PETITIONERS,

v.

FOOD & DRUG ADMIN., *ET AL.*,
RESPONDENTS.

On Petition for Writ of *Certiorari* to the U.S. Court of Appeals for the District of Columbia Circuit

REPLY IN SUPPORT OF PETITION FOR WRIT OF *CERTIORARI*

Lawrence J. Joseph
1250 Connecticut Ave. NW
Suite 200
Washington, DC 20036
Tel (202) 669-5135
Fax (202) 318-2254
Email ljj@larryjoseph.com

TABLE OF CONTENTS

Table of Contents i
Table of Authorities ii
Reply in Support of Petition for Writ of *Certiorari* ... 1
I. Plaintiffs Have Standing 2
A. Plaintiffs Satisfy Article III 3
1. Informational Standing 3
2. Competitive Standing 3
3. Authorizing Illegal Conduct 4
4. Procedural Standing 4
B. Plaintiffs Meet Prudential Standing 6
1. Zone Test Waived by Rule 6
2. Petitioners within Zone 6
3. Zone for *Ultra Vires* Actions 7
4. Suitable Challengers 8
II. FDA Cannot Require or Prove Exhaustion 8
A. FDA Cannot Require Exhaustion 9
B. FDA Did Not Prove Exhaustion 9
III. Non-Exhaustion Does Not Require Dismissal .. 11
A. Plaintiffs Satisfied Exhaustion 11
B. Exhaustion Is Futile 11
IV. If Plaintiffs Lack Standing, Ruling on Exhaustion Is *Dicta* 12
V. Lower Courts Must Follow Precedent and First-Decided Cases in Intra-Circuit Splits 12
Conclusion 13

TABLE OF AUTHORITIES

Cases

Ass'n of Am. Physicians & Surgeons, Inc. v. FDA, 539 F.Supp.2d 4 (D.D.C. 2009) 7

Ass'n of Am. Physicians & Surgeons, Inc. v. FDA, No. 07-0668-JDB (D.D.C. Aug. 22, 2008) 2

Banks v. Secretary, 997 F.2d 231 (7th Cir. 1993) 4

Bell v. Hood, 327 U.S. 678 (1946) 5

Cantrell v. City of Long Beach, 241 F.3d 674 (9th Cir. 2001) 2

Carey v. Population Services, Int'l, 431 U.S. 678 (1977) 7

Darby v. Cisneros, 509 U.S. 137 (1993) 9

Ethyl Corp. v. EPA, 306 F.3d 1144 (D.C. Cir. 2002) 5

F.J. Vollmer Co. v. Magaw, 102 F.3d 591 (D.C. Cir. 1996) 5

FAIC Securities, Inc. v. U.S., 768 F.2d 352 (D.C. Cir. 1985) 7

FEC v. Akins, 524 U.S. 11 (1998) 3

Graham v. FEMA, 149 F.3d 997 (9th Cir. 1998) 4

In re Columbia Gas Systems Inc., 33 F.3d 294 (3rd Cir. 1994) 2

Initiative & Referendum Institute v. Walker, 450 F.3d 1082 (10th Cir. 2006) 2

Lac du Flambeau Band of Lake Superior Chippewa Indians v. Norton, 422 F.3d 490 (7th Cir. 2005) 2

Larson v. Domestic & Foreign Commerce Corp., 337 U.S. 682 (1949) 8

Lujan v. Defenders of Wildlife,
504 U.S. 555 (1992) 3, 5

McCarthy v. Madigan, 503 U.S. 140 (1992) 11

McKart v. U.S., 395 U.S. 185 (1969) 9

MST Express v. Dep't of Transp.,
108 F.3d 401 (D.C. Cir. 1997) 4

New Jersey v. EPA,
517 F.3d 574 (D.C. Cir. 2008) 5-6

NRDC v. EPA, 824 F.2d 1146
(D.C. Cir. 1987) (*en banc*) 11

Pennhurst State School & Hosp. v. Halderman,
465 U.S. 89 (1984) 8

Singleton v. Wulff, 428 U.S. 106 (1976) 5

Steel Co. v. Citizens for a Better Environment,
523 U.S. 83 (1998) 12

Western Pacific R. Corp. v. Western Pacific R. Co.,
345 U.S. 247 (1941) 13

Statutes

Administrative Procedure Act,
5 U.S.C. §§551-706 ..... 9, 11

5 U.S.C. §704 11

Pediatric Research Equity Act of 2007, PUB. L.
NO. 110-85, tit. IV, §§401-404, 121 Stat. 823,
866-76 (Sept. 27, 2007) 1, 3

PUB. L. NO. 110-85, §402(b)(2), 121 Stat. 823, 875
(Sept. 27, 2007) 3

Rules, Regulations and Orders

21 C.F.R. §10.3(a) 9, 10, 11

21 C.F.R. §10.25(a) 2

21 C.F.R. §10.25(a)(1) 2

21 C.F.R. §10.45(e) 9, 10, 11

21 C.F.R. §10.85(d) 3, 6
21 C.F.R. §10.85(e) 3, 6
21 C.F.R. §314.50 2
40 Fed. Reg. 40,689 (1975) 6
42 Fed. Reg. 4688 (1977) 6
68 Fed. Reg. 66,113 (2003) 10
70 Fed. Reg. 52,050 (2005) 10
FED. R. CIV. P. 52(c) 5, 6

Other Authorities

Declaration of Ann Neimann 4

REPLY IN SUPPORT OF PETITION FOR WRIT OF *CERTIORARI*

Plaintiffs file this reply in support of their challenging the Food & Drug Administration ("FDA") supplemental new drug application ("SNDA") for the "Plan B" morning-after pill's dual prescription ("Rx")/over-the-counter ("OTC") distribution. Before addressing FDA's legal arguments, Plaintiffs respond to background issues raised by FDA's brief:

- FDA attempts to sweep Plan B into its decades-long practices for Rx-to-OTC switches (FDA Br. at 17) without acknowledging its *first-ever* dual Rx-OTC drug. One can reject dual Rx-OTC drugs without reaching true Rx-to-OTC switches.
- Although relying on Plan B's purported safety, *id.* at 14, FDA cannot dispute the failure to meet the Pediatric Research Equity Act ("PREA") data requirements for adolescents, including ones over 18. First Am. Compl. ¶¶92-95 (Court of Appeal Joint Appendix ("CAJA") 119-21).
- FDA's failure to establish Plan B's PREA safety for adolescent populations is particularly troubling given FDA's acquiescence to another court's baseless directive to lower Plan B's OTC age from 18 to 17, when that court premised its jurisdiction on mere *allegations* of standing, *see* Pet. at 5, contrasted with FDA's making strained arguments – disputing its own preambles – to defeat Plaintiffs' standing here.
- FDA suggests that Plaintiffs delayed proving exhaustion (FDA Br. at 9), when FDA refused to provide the non-public record and Plaintiffs moved to compel its production, provided links to public record excerpts before the initial decision,

and provided those record excerpts within two weeks of the court's implicitly denying Plaintiffs' motion by accepting defense counsel's unsworn testimony as the record. CAJA 199-206, 404-39, 441-51.

- Finally, FDA argues that SNDAs and §10.25(a) petitions constitute distinct paths for Rx-to-OTC switches, FDA Br. at 3, notwithstanding that SNDAs are a type of §10.25(a) petition. Pet at 7-11; 21 C.F.R. §§10.25(a)(1), 314.50. Significantly, this qualifies Plaintiffs as "interested persons" in a §10.25(a) petition under FDA's exhaustion rule.

With that background, Plaintiffs now respond to FDA's legal arguments against granting the petition.

I. PLAINTIFFS HAVE STANDING

Plaintiffs assert both constitutional and prudential standing, Pet. at 12-25, and FDA disputes both. FRA Br. at 9-17. Although FDA's arguments fail for the specific reasons outlined below, FDA's standing analysis also suffers the general flaw of consistently "confus[ing] standing with the merits." *Initiative & Referendum Institute v. Walker*, 450 F.3d 1082, 1092 (10th Cir. 2006); *Lac du Flambeau Band of Lake Superior Chippewa Indians v. Norton*, 422 F.3d 490, 501 (7th Cir. 2005); *In re Columbia Gas Systems Inc.*, 33 F.3d 294, 298 (3rd Cir. 1994); *Cantrell v. City of Long Beach*, 241 F.3d 674, 682 (9th Cir. 2001). If that were the test, every losing plaintiff would lack standing. Instead, standing asks whether, *under their legal views*, the plaintiffs suffer cognizable injury, caused by defendants, and redressable in court. Despite claims to the contrary, Pet. App. 40a, FDA and the lower courts consistently ignored Plaintiffs' merits views.

A. Plaintiffs Satisfy Article III

Plaintiffs make four standing arguments, Pet. at 13-21, and FDA rejects all four. FDA Br. at 11-17. Under *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-62 (1992), Plaintiffs have standing.

1. Informational Standing

FDA seeks to limit Plaintiffs' dispute with Plan B's labeling to "mislead[ing] their members" and indicating that "Plan B is safe." FDA Br. at 12. In fact, Plaintiffs seek statutorily required Rx-versus-OTC labeling and safety data (both online[1] and on labels) for professional reasons. Pet. at 13-16. Suggesting that drug labeling is not required information (FDA Br. at 11-12) would be dubious, even if FDA had not legislatively bound itself to the contrary in preamble statements. Pet. at 14 & n.3; 21 C.F.R. §10.85(d)-(e). On redressability, FDA reprises the losing federal arguments from *FEC v. Akins*, 524 U.S. 11, 25 (1998). Reversing FDA's SNDA and remanding – for a rulemaking or an SNDA – would redress Plaintiffs' injuries enough for Article III.

2. Competitive Standing

Under binding circuit precedent, increased competition – distinct from lost revenue – represents cognizable Article III injury. Pet. at 16-17 (collecting cases). Relying on those precedents, Plaintiffs established exposure to competition by both an

---

[1] Under PREA's integration clause, vacating FDA's SNDA would leave Plan B "pending on or after the date that is 1 year prior to the date of [PREA's] enactment." Pet. App. 49a.

affiant and their complaint,[2] but the courts required more (lost revenue) than circuit precedent requires. Even if this Court affirms those courts' moving the goalposts, due process would compel remanding to provide Plaintiffs the opportunity to address the moved goalposts.

3. Authorizing Illegal Conduct

FDA and the courts below suggest that any change in circumstances is "attributable to the independent decisions of patients who now may choose whether or not to consult their doctor before using Plan B." FDA Br. at 13. That simply ignores that, prior to FDA's challenged SNDA, patients could obtain Rx-only Plan B only from physicians. Pet. at 18-19; *accord Graham v. FEMA*, 149 F.3d 997, 1003 (9th Cir. 1998) (independent-decision argument fails when prior law constrained those decisions); *Banks v. Secretary*, 997 F.2d 231, 241 (7th Cir. 1993) (same). The decisions below conflict not only with binding precedents but also with common sense. Injuries from OTC access obviously flow from FDA's decision to allow OTC access in the first place.

4. Procedural Standing

The parties agree that Plaintiffs must suffer non-procedural injury before they may assert procedural standing. *Compare* Pet. at 13 *with* FDA Br. at 15-16. They diverge, however, in applying procedural-standing doctrines. Plaintiffs argue that their procedural injuries – such as FDA's failure to

---

[2] In addition, the manufacturer showed that OTC status doubled Plan B's sales. Mot. to Intervene, Ex. A, ¶¶48-49 (Neimann Declaration).

convene required rulemakings – lower the threshold for immediacy and redressability because those procedures are "designed to protect [the] threatened concrete interest of [theirs] that is the basis of [their] standing." Pet. at 19-20 (*quoting Defenders of Wildlife*, 504 U.S. at 573 n.8). FDA argues that Plaintiffs' procedural argument lacks merit and so provides no basis for review. FDA Br. at 16. FDA confuses standing with the merits, notwithstanding that standing assumes Plaintiffs' merits views.

That said, Plaintiffs encourage the Court to reach the procedural merits under either Plaintiffs' Rule 52(c) motion or the need to discard "wholly insubstantial and frivolous" arguments "made solely for the purpose of obtaining jurisdiction." *Bell v. Hood*, 327 U.S. 678, 682-83 (1946). The procedural merits are straightforward, purely legal, and thus decidable here. *Singleton v. Wulff*, 428 U.S. 106, 120-21 (1976). Basically, FDA argues its four-decade practice, FDA Br. at 17,[3] and Plaintiffs argue that FDA's own rules require rulemakings to switch Rx drugs to OTC status. Pet. at 7-11. Even if FDA's own rules did not preclude FDA's position, FDA's general-purpose authority to approve drug applications by order cannot trump its special-purpose authority to switch drugs to OTC status by rulemaking. *Ethyl Corp. v. EPA*, 306 F.3d 1144, 1148-50 (D.C. Cir. 2002); *MST Express v. Dep't of Transp.*, 108 F.3d 401, 403, 406 (D.C. Cir. 1997); *New Jersey v. EPA*,

---

[3] Courts "do not see how merely applying an unreasonable statutory interpretation for several years can transform it into a reasonable interpretation," *F.J. Vollmer Co. v. Magaw*, 102 F.3d 591, 598 (D.C. Cir. 1996).

517 F.3d 574, 582-83 (D.C. Cir. 2008). Whether to resolve Plaintiffs' Rule 52(c) motion or to assure itself of its jurisdiction, the Court can answer FDA's *merits* argument on the applicable procedures.

B. Plaintiffs Meet Prudential Standing

Plaintiffs argue that prudential standing is not applicable, is met, and provides no basis for dismissal even if not met. Pet. at 21-25. FDA's responses lack merit.

1. Zone Test Waived by Rule

Plaintiffs argue that FDA *legislatively* waived prudential standing in legislative rules that bind FDA to its preamble statements that waive standing. Pet. at 21 (*citing* 21 C.F.R. §10.85(d)-(e); 40 Fed. Reg. 40,689 (1975); 42 Fed. Reg. 4688 (1977)). FDA responds that litigants cannot waive standing, FDA Br. at 15, which is simply inapposite to Plaintiffs' legislative-waiver argument. This Court should address the important question of whether agencies with delegated legislative authority can legislatively waive the Judiciary's prudential doctrines.

2. Petitioners within Zone

FDA cannot contest that pharmacists' right to clear Rx-versus-OTC labeling falls at the dead center of the underlying statutes' interests. FDA questions only whether pharmacists face imminent injury *from enforcement*. FDA Br. at 7. Beyond any *potential* enforcement issues, however, drug labeling constitutes an *extant* informational injury.

FDA also argues that economic competition is outside – even antithetical to – the zone for safe drugs. FDA Br. at 14. FDA again fails to consider Plaintiffs' merits views in analyzing standing: *Plan B is not safe* for adolescents, including adolescents

over 18 (now 17) years old. First Am. Compl. ¶¶92-95 (CAJA 119-21). The relative interests of doctors and pharmacists fall easily within the statute's zone.

Finally, FDA argues that Plaintiffs cannot "mix-and-match one interest [to satisfy] Article III ... and a different interest [to satisfy] the zone-of-interest test." FDA Br. at 14. Physicians can, however, satisfy the zone-of-interest test for *patients'* Article III injuries if the physicians have Article III standing, close relationships with patients, and something hinders patients' bringing suit. *Carey v. Population Services, Int'l*, 431 U.S. 678, 682-86 (1977) (vendor with constitutional standing can assert *potential* customers' privacy rights); *FAIC Securities, Inc. v. U.S.*, 768 F.2d 352, 357-61 (D.C. Cir. 1985) (Scalia, J.). Here, patients lack imminent injury for emergency-contraceptive access, Pet. App. 22a-23a, and patients lack incentive to sue. First Am. Compl. ¶22 (CAJA 97). Physicians suffering competitive injuries can meet the zone-of-interests test with patients' (and potential patients') statutory rights to safe drugs and labeling.

3. Zone for *Ultra Vires* Actions

Plaintiffs argue that *ultra vires* agency action does not trigger the underlying statute's narrow zone of interests because the test either is inapposite or implicates the separation-of-powers doctrine's wider zone of interests. Pet. at 23-24. FDA premises its defense on its action's being *intra vires*, calling it *undisputed* that FDA can approve Rx-to-OTC switches. FDA Br. at 15. Plaintiffs dispute not only FDA's authority for Rx-to-OTC switches *without a rulemaking* but also FDA's suggestion that dual Rx-OTC labeling even qualifies as an Rx-to-OTC switch. Certainly, the final product is not OTC.

Relying on an out-of-context *Larson* quotation in *Pennhurst State School & Hosp. v. Halderman*, 465 U.S. 89 (1984), FDA would exclude from the *ultra vires* doctrine agencies' mere errors in exercising delegated power. FDA Br. at 15. Because it involved an agency delegated "broad discretion to provide 'adequate' mental health services" and plaintiffs who argued "that [officers] have not provided such services adequately." *Pennhurst*, 465 U.S. at 102, *Pennhurst* could not erase the bright line that "where the officer's powers are limited by statute, his actions beyond those limitations are considered individual and not sovereign actions." *Larson v. Domestic & Foreign Commerce Corp.*, 337 U.S. 682, 689 (1949). The Court should affirm the definition of "*ultra vires*" and define the applicable zone of interests.

4. Suitable Challengers

Under a line of circuit authority, competitors satisfy the zone-of-interest test when suing to enforce statutory demarcations, like entry restrictions. Pet. at 25 (collecting cases). FDA offers nothing in response to these binding authorities.

II. FDA CANNOT REQUIRE OR PROVE EXHAUSTION

FDA's mandatory exhaustion rules cannot bar review for two principal reasons. First, FDA's rules are *ultra vires* because they fail to hold agency action inoperative pending intra-agency review and cover purely legal issues that common-law exhaustion would not bar. Second, FDA bears the burden of proving non-exhaustion but cannot meet it because FDA refused to certify the administrative record, which is the only basis for FDA to meet its burden.

Pet. at 25-30. FDA's contrary arguments (FDA Br. at 17-19) simply avoid these issues.

A. FDA Cannot Require Exhaustion

FDA fails to respond to Plaintiffs' argument that exhaustion does not apply to issues that are "solely one[s] of statutory interpretation" where "the proper interpretation [was] certainly not a matter of [agency] discretion" or the agency "has clearly exceeded its jurisdiction." Pet. at 26 (*quoting McKart v. U.S.*, 395 U.S. 185, 194, 197-99 (1969)). For Counts II through VII, that eliminates exhaustion as a basis for dismissal.

FDA cites *Darby v. Cisneros*, 509 U.S. 137, 153 (1993), for agency rules' continuing exhaustion doctrines in Administrative Procedure Act ("APA") cases, FDA Br. at 8, without addressing FDA's failure to hold agency action inoperative pending intra-agency review, APA's prerequisite to barring review: "Otherwise, the initial decision becomes final and the aggrieved party is entitled to judicial review." Pet. at 27 (*quoting Darby*, 509 U.S. at 152). To sidestep *Darby*, FDA argues that Plaintiffs did not file petitions, FDA Br. at 18-19, which is irrelevant because FDA's rules apply to interested persons (*i.e.*, petitioners and commenters), not just petitioners. 21 C.F.R. §§10.3(a), 10.45(e). The factual question of Plaintiffs' status as "interested persons" falls squarely within the split authority on which party bears the burden of proving exhaustion.

B. FDA Did Not Prove Exhaustion

To avoid the split in authority over who bears the burden of proving exhaustion, Pet. at 29-30 & n.7, FDA argues the *non sequitur* that Plaintiffs did not file petitions. FDA Br. at 19. One can satisfy

FDA's rules by filing comments or objections, 21 C.F.R. §§10.3(a), 10.45(e), which Plaintiffs did. Indeed, Plaintiffs are "interested" twice over, Pet. at 31 (*citing* 68 Fed. Reg. 66,113 (2003); 70 Fed. Reg. 52,050 (2005)), and FDA disputes only whether the 2005 notice related specifically to Plan B. FDA Br. at 18. By contrast, the 2003 notice plainly related to "new drug application 21-045, proposing over-the-counter use of Plan B." 68 Fed. Reg. at 66,113.[4] If FDA bears the burden of proof, it cannot meet it, even accepting FDA's view of the 2005 proceeding.

FDA's Commissioner testified to Congress that the 2005 proceeding joined with the SNDA and, indeed, provided FDA's basis to approve dual Rx-OTC Plan B. Pet. at 32. Moreover, Plaintiffs' 2005 comments specifically state that the "groups also oppose the Rx-to-OTC switch of Plan B®." CAJA 405. Without the administrative record, no-one can *know* whether Plaintiffs' comments were part of the Plan B proceeding, although it seems unlikely that FDA's Commissioner would have lied about that in his congressional testimony. Plaintiffs satisfy the interested-person test from the 2003 proceeding and appear to do so for 2005 as well. Resolving the issue requires resolving the split authority on who bears the burden of proving exhaustion.

---

[4] FDA's transcript shows wide participation – including Plaintiffs' representatives and members – in the 2003 process. http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4015T1.htm (last visited Jan. 3, 2011).

III. NON-EXHAUSTION DOES NOT REQUIRE DISMISSAL

Non-exhaustion would not warrant dismissal, even if FDA's exhaustion rules survive Plaintiffs' challenge. First, plaintiffs satisfied FDA's rules. Second, exhaustion is futile because FDA considered Plaintiffs' arguments and opposed them below on the merits. Pet. at 30-33. FDA's responses are meritless.

A. Plaintiffs Satisfied Exhaustion

As indicated, Plaintiffs met FDA's exhaustion rule by commenting on Plan B. *Accord* Pet. at 30-32. FDA's argument that only *petitioners* exhaust its rule defies the rule's plain language. 21 C.F.R. §§10.3(a), 10.45(e). Even if FDA's position could satisfy §704 *for APA review*, Plaintiffs would meet common-law exhaustion for officer suits in equity.

B. Exhaustion Is Futile

Petitioning FDA would be futile for two reasons, vitiating any need to exhaust FDA remedies at common law. First, Plaintiffs presented their arguments to FDA, and FDA rejected them. Pet. at 32-33. Second, FDA opposed Plaintiffs' claims on the merits in this litigation, rejecting them *again*. *Id.* at. 33. Both rationales make further resort to FDA futile and, for equity purposes, "inadequate." *McCarthy v. Madigan*, 503 U.S. 140, 148 (1992). FDA's suggestion that Plaintiffs failed to raise these arguments below (FDA Br. at 19) is wrong. Pls.' Opp'n. to Mot. to Dismiss, at 30-32; Pls.' Post-J. Mot. at 33-34; Pls.' Reply in Supp. of Post-J. Mot. at 22. Moreover, even non-exhaustion is excused if the agency, in fact, considered a plaintiff's issue, *NRDC v. EPA*, 824 F.2d 1146, 1150-1152 (D.C. Cir. 1987) (*en banc*), and

this Court cannot know what FDA considered without the administrative record.

IV. IF PLAINTIFFS LACK STANDING, RULING ON EXHAUSTION IS *DICTA*

Plaintiffs argue that – because Count VIII seeks to vacate FDA's exhaustion rules on the merits – the lower courts' dismissal for non-exhaustion under FDA's exhaustion rule reaches the merits, which those courts lacked jurisdiction to do if Plaintiffs lack standing. Pet. at 33-35. The best that FDA can offer is that "it *may not* have been improper for the courts [to address] exhaustion" because courts "treat[] exhaustion as jurisdictional in *some instances*." FDA Br. at 19 (emphasis added). Then, arguing that this Court reviews judgments, not decisions, FDA argues that it would serve little purpose to grant *certiorari* to affirm dismissal on a subset of the grounds below. *Id.* Plaintiffs disagree.

Courts have the *obligation* not to reach the merits if plaintiffs lack standing. *Steel Co. v. Citizens for a Better Environment,* 523 U.S. 83, 95 (1998). "*Maybe*" and "*some*" miss the mark. Indeed, given that Count VIII challenged FDA's exhaustion rules, FDA's judgment-decision dichotomy is misplaced: the judgment *reaches the merits* of Count VIII. Because reviewing unlawful FDA action matters beyond this one drug, Pet. at 34-35, exhaustion requires this Court's review even if standing does not.

V. LOWER COURTS MUST FOLLOW PRECEDENT AND FIRST-DECIDED CASES IN INTRA-CIRCUIT SPLITS

Circuit precedent unquestionably supports Plaintiffs on standing and exhaustion. Pet. at 35 n.10. Without disputing that, FDA downplays intra-

circuit splits' relevance to this Court's supervisory jurisdiction. FDA Br. at 13. Plaintiffs disagree.

Although appellate courts may adopt "[a]ny procedure ... which is sensibly calculated to achieve these dominant ends of avoiding or resolving intra-circuit conflicts." *Western Pacific R. Corp. v. Western Pacific R. Co.*, 345 U.S. 247, 271 (1941), this Court retains the "general power to supervise the administration of justice in the federal courts," and "the responsibility lies with this Court to define [the] requirements and insure their observance." *Id.* at 260 (interior quotations omitted). Given the lower courts' failure to follow or overturn circuit precedent, that task falls to this Court.

CONCLUSION

The Court should grant the petition.

January 3, 2011

Respectfully submitted,

Lawrence J. Joseph
1250 Connecticut Ave. NW
Suite 200
Washington, DC 20036
Tel: (202) 669-5135
Fax: (202) 318-2254
Email ljj@larryjoseph.com